

## **REMARKS**

Claims 53-60 are presently pending in the case. Claims 61-68 have been cancelled due to the finality of the restriction requirement. Claims 53-60 have been rejected. Reconsideration of the present case in view of the remarks herein is requested.

### **Drawing Objections**

The Drawings were objected to on the form PTO 948 by the Draftsperson. Substitute drawings are enclosed.

### **Claim rejections under judicially created doctrine of Double Patenting**

The Examiner rejected claims 53 and 54 under the judicially created doctrine of double patenting as being unpatentable over the claims of U.S. Patent 6,606,992.

To expedite prosecution of the present case, Applicant submits herewith a terminal disclaimer in compliance with 37 CFR 1.321(c) in accordance with the Examiner's suggestion. It is requested that the double patenting rejection be removed in view of this disclaimer.

### **Claim rejections under 35 USC 102**

The Examiner rejected claims 53-55, 57 and 59 under 35 USC 102(b) as being anticipated by U.S. Patent 5,727,546 to Clarke et al (hereinafter Clarke et al). The rejection is traversed.

Clark et al does not anticipate claims 53-55, 57 and 59. To sustain a section 102 rejection, the reference relied upon, must disclose each and every element of the claimed invention. Non-disclosure of a single element of the claim negates anticipation. Independent claim 53, for example, is to a method for aerosolizing a pharmaceutical formulation, the method comprising, inter alia, providing a valve to prevent respiratory gases from flowing to the lungs when a user attempts to inhale, and then abruptly permitting respiratory gases to flow to the lungs

by opening the valve when a threshold actuating vacuum caused by the attempted inhalation is exceeded, and providing a flow regulator within the airway, wherein the flow regulator varies the flow resistance through the airway to control the flow of respiratory gases. Clarke et al does not provide both a threshold valve and a flow regulator. It is respectfully submitted that this positively recited feature is absent in the disclosure of Clarke et al, thereby precluding a section 102 rejection because each and every element of the claim is not taught by the cited reference. Thus, the Examiner is respectfully requested to reconsider the language of claim 53 and the claims depending therefrom and to withdraw the rejection thereunder.

**Claim rejections under 35 USC 103(a)**

The Examiner rejected claims 58 and 60 under 35 USC 103(a) as being unpatentable over Clarke et al. The rejection is traversed.

Clarke et al does not render claims 58 and 60 unpatentable. Claims 58 and 60 depend from claim 53 which is not rendered unpatentable by Clarke et al for the reasons given above. Since claims 58 and 60 depend from an allowable claim, they too are allowable. In addition, claim 58 is allowable over Clark et al in that Clarke et al fails to disclose or teach the duckbill valve recited in the claim. Claim 60 is also not rendered unpatentable by Clarke et al in that claim 60 recites a parallel flow arrangement that is not disclosed or taught by Clarke et al.

The Examiner rejected claim 56 under 35 USC 103(a) as being unpatentable over Clarke et al in view of U.S. Patent 6,116,237 to Schultz et al (hereinafter Schultz et al). The rejection is traversed.

Claim 56 depends from allowable claim 53. Since Schultz et al does not make up for the deficiencies discussed above with regard to Clarke et al, the combination of Clarke et al and Schultz et al also fails to render claim 56 unpatentable.

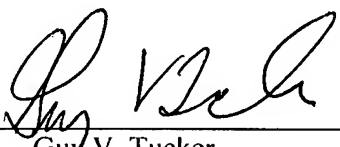
**Conclusion**

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

NEKTAR THERAPEUTICS  
(formerly INHALE THERAPEUTIC  
SYSTEMS)

Dated: 27 SEP 2007

By:   
Guy V. Tucker  
Reg. No. 45,302

Please send all correspondence to:  
Guy Tucker  
Nektar Therapeutics  
(formerly Inhale Therapeutic Systems, Inc.)  
201 Industrial Road  
San Carlos, CA 94070  
Phone: (650) 620-5501  
Fax: (650) 620-6395